Quality Assurance & Regulatory Affairs
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Unexpected Shutdown

There is a remote possibility that your AED 10 could unexpectedly shut down during use. This remote possibility can exist only if **both** of the following conditions are met:

A. The pads are attached to the patient **prior to** turning on the device (contrary to the instructions for use on the back of the unit and also in the Quick Reference material inside the AED 10 case.); **and**

B. The device is set to deliver an initial shock of 150 Joules energy.

The unexpected shutdown described above cannot occur if the AED 10 is set to deliver an initial shock of 200 Joules energy. There has been one known death during an event in which the combination of these conditions caused the device to shut down.

The 10,735 units that may have this defect were manufactured between October 3, 2002 and December 30, 2004. Table 3 in Appendix A, below, lists the serial numbers of all affected units.

All of the recalled units will be upgraded with software that corrects the unexpected shutdown problem. In the meantime, until your device is upgraded, if the initial shock is set to 150J, it is **vital** to follow the step 1-2-3 operating procedure which directs attachment of the pads after the device has been turned on. This procedure is described on the back of your device and also in the Quick Reference material inside the AED 10 case. Some pages in the user's manual may erroneously describe or show illustrations of an operating procedure in which the pads are attached before the device is turned on. Please disregard these erroneous instructions; a corrected user's manual will be distributed by separate correspondence.

Please be advised that all U.S. units and most international units have a factory default setting of 200J initial shock that can only be changed using the password-protected supervisor menu. Only units sold outside the U.S. with the British voice option have a factory default setting of 150J initial shock.